UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,134	02/11/2005	Scott Koenig	13789-105023	1503

65989 7590 09/24/2007

KING & SPALDING
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-4003

EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
09/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,134	KOENIG ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007 and 25 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 32-110* is/are pending in the application.

4a) Of the above claim(s) *2-8,22,24-29,33,35-37,39,40,44-80 and 91-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 9-21, 23, 30, 32, 34, 38, 41-43, 81-90, 104-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on June 29, 2007, has been entered.

2. Applicant's amendment to the claims, filed on April 25, 2007, has been entered.

Claim 31 has been canceled.
Claim 110 has been added.

Claims 1-30 and 32-110 are pending.

Claims 2-8, 22, 24-29, 33, 35-37, 39, 40, 44-80, 91-103 have been withdrawn from further consideration, as being drawn to nonelected inventions.

Claims 1, 9-21, 23, 30, 32, 34, 38, 41-43, 81-90, 104-110 are currently under consideration as they read on originally elected invention of an isolated antibody of clone 2B6 without conjugation that binds to native FcγRIIB with greater affinity than FcγRIIA and antagonizes at least one activity of FcγRIIB.

3. This Office Action is in response to Applicant's amendments to the claims and remarks filed on April 25, 2007 and June 29, 2007.

The rejections of record can be found in the previous Office Actions, mailed on April 10, 2006 and December 29, 2006.

4. The reference of Oxford Dictionary of Biochemistry and Molecular Biology, submitted by applicant, on April 25, 2007, has been listed on PTO-892 and the copy of the reference will not be supplied.

5. In light of applicant's amendment to the claims, the prior rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 102(b) and 103(a) have been withdrawn.

6. In view of applicant's amendment to the claims, the prior rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) have been withdrawn.

7. Claim 34 is objected to because it is dependent upon withdrawn claim 33. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

Applicant added claims 108 and 109 on January 30, 2006.

The phrases "variable domain specifically binds Daudi cells" as recited in claim 108 and "variable domain does not specifically bind denatured FcγRIIB" in claim 109, are not supported by the original disclosure or claims as originally filed.

Applicant's amendment, filed on January 30, 2006, directs to support in the specification for claims 108 and 109 to page 12, lines 12-18 and page 20, lines 16-20, and page 60, lines 6-15 and asserts that no new matter has been added.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitations". The specification does not provide sufficient support for an isolated antibody or fragment thereof comprising variable domains that specifically binds the extracellular domain of FcγRIIB with greater affinity than FcγRIIA, wherein said variable domains specifically binds Daudi cells or does not specifically bind denatured FcγRIIB. The specification only disclose an isolated antibody or fragment thereof comprising variable domains that specifically binds the extracellular domain of FcγRIIB with greater affinity than FcγRIIA, (see page 15, in particular) and Daudi cells as target cells in antibody dependent cell-mediated cytotoxicity (ADCC) assay (see lines 19-20 on page 61, in particular); the instant claims now recite an antibody with variable domains specifically binds Daudi cells or does not specifically bind denatured FcγRIIB, which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure (an isolated antibody or fragment thereof comprising variable domains that specifically binds the extracellular domain of FcγRIIB with greater affinity than FcγRIIA) and possibly limited species (e.g. antibody clone 2B6 or 3H7) do not provide sufficient direction and guidance to the features currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 9-17, 21, 23, 30, 32, 34, 42, 81-90, 104, 105, and 107-110 are rejected under 35 U.S.C. 102(e) as anticipated by Ravetch (WO 01/79299, reference B04 on IDS filed on July 15, 2005).

Ravetch teaches monoclonal antibody that specific binds human FcγRIIB but not FcγRIIA (see page 37, in particular). Further, Ravetch teaches that the anti-FcγRIIB antibody can be used as competitive inhibitors to prevent the binding of tumor specific antibody to the FcγRIIB and to amplify the effect of antibody dependent cytotoxicity (e.g. see 1st –3rd paragraphs on page 13, in particular). Furthermore, Ravetch teaches that the anti- FcγRIIB antibody can be IgG (e.g. see 2nd paragraph on page 11), humanized (see last paragraph on page 12, in particular) and single chain antibody (e.g. see 2nd paragraph on page 11). Moreover, Ravetch shows that FcγRIIB is an inhibiting receptor containing an immunoreceptor tyrosin-based inhibition motif (ITIM) in its cytoplasmic domain; engaging FcγRIIB would lead to phosphorylation of ITIM and recruitment of inositol polyphosphate 5 phosphatase SHIP, thereby prevents activation of PLCγ and abrogates calcium influx (e.g. see 1st paragraph on page 3). In addition, Ravetch teaches that the anti- FcγRIIB antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers (e.g. see 2nd and 3rd paragraphs on page 26).

Ravetch also teaches that the antibody can have a variant Fc region comprising at least one amino acid modification (see last paragraph on page 9, in particular) and have altered affinity to an Fcγ receptor and such antibody is able to enhance antibody-mediated cytotoxicity in the presence of human effector cells than a parent antibody (see 5th and 6th paragraphs on page 13 and 3rd-4th paragraph on page 14, in particular).

Given that the reference teaches that anti-FcγRIIB antibody prevents binding of monomeric molecules to the FcγRIIB and prevents crosslinking of the FcγRIIB (e.g. see 1st paragraph on page 13), the prior art anti- FcγRIIB antibody would inherently bind the extracellular domain of the FcγRIIB and not the denatured FcγRIIB.

Further, it is noted that when claims recite using an old composition or structure (e.g. anti-FcγRIIB antibody) and the use is directed to a result or property of that composition or structure, then the clams are anticipated. See MPEP 2112.02. Also, see Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

Here, given the prior art antibodies have the same property of binding the extracellular domain of FcγRIIB with greater affinity than FcγRIIA; the functional limitations recited in claims 9-15, 30, 32, and 108-110 would be inherent properties of the prior art anti-FcγRIIB antibody. Also, the Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP 2112-2113 for case laws on inherency.

Furthermore, the process limitation encompassed in claim 34 is not seen as further limiting the claimed antibody and it is presumed that equivalent antibodies can be obtained by multiple methods. The patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Given that the prior art antibodies specifically bind FcγRIIB with greater affinity than FcγRIIA, the prior art antibodies read onto the instant claim 34.

Moreover, although the reference is silent about the disclosed antibodies competing for binding with the claimed monoclonal antibody produced by clone 2B6 (see instant claim 42) and the reference is silent about the disclosed antibodies binding to the extracellular domain of FcγRIIB with at least 2 times greater or $4\text{-}10^6$ times greater affinity than FcγRIIA (see instant claims 23 and 81-89), it does not mean that the referenced antibodies do not bind the same epitope as the claimed monoclonal antibody and have the recited affinities as compared to binding to FcγRIIA. Since the referenced antibodies selectively bind FcγRIIB and do not bind FcγRIIA and are competitive inhibitors, the referenced antibodies comprise the structural limitations of the claimed antibody (e.g. see 1st paragraph on page 37). As such, the referenced antibodies specific to FcγRIIB comprise the properties of at least 2 times greater affinity or $4\text{-}10^6$ times greater affinity than binding to FcγRIIA as recited in instant claims 23 and 81-89.

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody do not compete for binding with monoclonal antibody produced by clone 2B6 recited in the claim 42 and do not have at least 2 times greater affinity or $4\text{-}10^6$ times greater affinity than binding to FcγRIIA. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald* et al., 205 USPQ 594 (CCPA 1980).

Therefore, the reference teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 18, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravetch (WO 01/79299, reference B04 on IDS filed on July 15, 2005) in view of Reff et al. (Critical Review in Oncology/Hematology. 2001. 40:25-35, of record on PTO-892 mailed on April 10, 2006).

The teachings of Ravetch have been discussed, supra, in Section 12.

The reference teachings differ from the claimed invention by not describing human antibody and the antigen-binding fragments $F(ab')_2$ and F(ab).

Reff et al. disclose that human antibody is better tolerated in human and human antibody can be made using various techniques including transgenic mice where the murine Ig genes have been replaced with human IgG genes or recobinatn human antibody libraries (see right column of page 27 and 1st paragraph on the left column of page 28, in particular). Further, Reff et al. teach smaller versions of antibodies including antigen-bindign fragments F(ab) and $F(ab')_2$ have been made to achieve better penetration of the avascular tumors than whole antibody (see Figure 2 on page 27 and right column on page 28, in particular).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to make human anti-FcγRIIB specific antibody and antigen-binding fragments F(ab) and $F(ab')_2$ thereof. The ordinary artisan would have been motivated to do so for human therapies because Ravetch teach that anti- anti-FcγRIIB antibody that does not bind FcγRIIA is useful in abrogating the inhibitory activity of the anti-FcγRIIB and thereby enhancing the effectiveness of cytotoxic activity of IgG antibody (e.g. see 3rd paragraph on page 13) and Reff et

al. teach human antibody is better tolerated in human and antigen-binding fragments F(ab) and $F(ab')_2$ penetrate better to avascular tumors than whole antibody.

Using the known techniques to provide human anti-FcγRIIB antibody and antigen-binding fragments F(ab) and $F(ab')_2$ for the desired properties of better tolerance in human and better tumor penetration would have been obvious to one of ordinary skill. A person skill in the art would have reasonable expectation of success because making human antibody and antigen-binding fragments $F(ab')_2$ and F(ab) are routine in the art as taught by Reff et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 1, 104, and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravetch (WO 01/79299, reference B04 on IDS filed on July 15, 2005) in view of Presta (US Patent 6,737,056, of record on PTO-892 mailed on April 10, 2006).

The teachings of Ravetch have been discussed, supra, in Section 12.

The reference teachings differ from the claimed invention by not describing an antibody comprising an Fc region with at least one amino acid modification wherein the Fc region binds FcγRIIIA with higher affinity than wild-type Fc region.

Presta identifies the amino acid residues in the Fc region that interacts with Fcγ receptor and teaches that such amino acid residues in the Fc region can be modified to enhance the Fc binding with Fc receptor FcγRIIIA expressed on NK cells and NK cells are effector cells mediate antibody-dependent cell-mediated cytotoxicity (ADCC) (see column 2 and claims 13-16, in particular). Further, Presta teaches that the Fc region of antibodies can be modified by amino acid substitutions, e.g. E334A mutation in the Fc region for enhanced binding affinity of the Fc

region to FcγRIIIA and enhanced effector functions such as (see 5th and 6th paragraphs in column 5, claims 13-16, and Table 6 on columns 59 and 60, in particular).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to make human anti-FcγRIIB specific antibody and to modify amino acid residues in the Fc regions for enhanced binding affinity for FcγRIIIA. The ordinary artisan would have been motivated to do so because Ravetch teach that anti- anti-FcγRIIB antibody that does not bind FcγRIIA is useful in abrogating the inhibitory activity of the anti-FcγRIIB and thereby enhancing the effectiveness of cytotoxic activity of IgG antibody (e.g. see 3rd paragraph on page 13) and Presta teaches that the Fc region of an antibody can be modified to have enhanced binding affinity to FcγRIIIA for enhanced ADCC.

Using the known techniques to provide monoclonal anti-FcγRIIB antibody with at least one amino acid modification in the Fc region for enhanced binding affinity to FcγRIIIA for enhanced ADCC would have been obvious to one of ordinary skill. A person skill in the art would have reasonable expectation of success because making amino acid modification is routine in the art and the person skill in the art would know what positions in the Fc region can be modified based on the teachings of Presta.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 9-21, 23, 30, 32, 34, 38, 41-43, 81-90, 104-110 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending USSN. 11/305,787.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending applications claims are drawn to same or nearly the same anti-FcγRIIB antibody or fragment thereof that specifically binds the extracellular domain of human FcγRIIB and anti-FcγRIIB antibody with Fc modification. Given antibodies rely on the same antigen specificity of the extracellular domain of the FcγRIIB and amino acid modification in the Fc region, the conflicting claims would anticipate the instant claims. Further, claims 14-15 of the copending USSN 11/305,787 recite specific amino acid substitutions in specific position of the Fc region, while the instant claims 104-107 recite a genus

of at least one modification in the Fc region; as such, the species recited in the copending claims would anticipate the genus of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1, 9-21, 23, 30, 32, 34, 38, 41-43, 81-90, 104-110 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and claims 53-64 of copending USSN 11/108,135.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending applications claims are drawn to same or nearly the same anti-FcγRIIB antibody or fragment thereof that specifically binds the extracellular domain of human FcγRIIB and anti-FcγRIIB antibody with Fc modification. Given antibodies rely on the same antigen specificity of the extracellular domain of the FcγRIIB and amino acid modification in the Fc region, the conflicting claims would anticipate the instant claims. It is further noted that the copending claims 11-13 and copending claims 61-64 of USSN 11/108,135 recite additional limitations that are not encompassed by the instant claims, e.g. anti-FcγRIIB antibody or fragment thereof conjugated to a therapeutic agent in copending claims 11-13 and pharmaceutical composition comprising additional anti-cancer agents in copending claims 61-64; as such, the copending claims would anticipate the instant claims. Furthermore, claims 7, 8, 59, and 60 recite species of specific amino acid substitutions in specific position of the Fc region, while the instant claims 104-107 recite a genus of at least one modification in the Fc region. As such, the species recited in the copending claims would anticipate the genus of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1, 9-21, 23, 30, 32, 34, 81-90, 104-110 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 108-124 of copending USSN 10/643,857.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending applications claims are drawn to same or nearly the same anti-FcγRIIB antibody or fragment thereof that specifically binds the extracellular domain of human FcγRIIB and anti-FcγRIIB antibody with Fc modification. Further, copending claims 108-124 recite monoclonal antibodies produced by specific clones (eg. Clone 1D5 having ATCC accession no. PTA-5958 as recited in the copending claim 108), as such the species of the specific antibodies would anticipate the claimed genus of anti-FcγRIIB antibody or fragment thereof recited in the instant claims. Furthermore, copending claims 112-114 recite additional limitation of antibody "conjugated to a therapeutic agent" that is not recited in the instant claims; therefore, the copending claims would anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. It is noted that applicant acknowledged that the copending USSNs 11/108,135, 11/305,787 and the instant application were commonly owned by MacroGenics Inc at the time the invention was made (see page 22 of the Remarks, filed 10/10/2006).

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder, Ph.D.
Patent Examiner
September 12, 2007